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IRVINE, CA 92614			3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/621,196	SHACHAR, YEHOASHUA	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael Apanius	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 21-30 and 51-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 31-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20060928</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This office action is in response to the amendment filed on 7/27/2006. The amendment is entered. The amendments to claims 1, 3, 4, 6, 7, 9, 13, 14, 19, 31-36, 39-41, 47, 48 and 50; the amendments to the specification; and the replacement drawing sheets are acknowledged. Currently, claims 1-66 are pending and claims 21-30 and 51-66 remain withdrawn from consideration. It is noted that claim 20 in the claim listing is inaccurately labeled as "Withdrawn".

#### ***Information Disclosure Statement***

2. All of the references on the IDS of 9/28/2006 have already been listed and considered on a previous IDS.

#### ***Drawings***

3. It is noted that the Applicant stated on page 42 of the amendment that Fig 1A has been amended. However, a replacement sheet for figure 1A was not submitted with the amendment.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the magnetic circuits set forth in amended claims 1 and 31 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include reference character that appear to not be mentioned in the description: for example, "2" in figure 2; "49" in figure 4; "104X" in figure 7; "104Y" in figure 8; "104Z" in figure 9; "155" in figure 10; "921", "922", "926", "929", "930" in figures 13D-13H; "800" in figure 17B; "610" and "611" in figure 18C.
6. The drawings are further objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 311-314 and 316-319. It appears that these reference characters should be in figures 8 and 9, respectively.
7. The drawings are even further objected to because some characters are not readable and not all lines are clean or uniformly thick and well-defined. See 37 CFR 1.84 (l). For example, the characters below element 4 in the replacement sheet for fig. 2 are illegible.
8. Corrected drawing sheets in compliance with 37 CFR 1.121(d) and/or amendments to the specification in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

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consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

9. The abstract of the disclosure is objected to because it contains more than 150 words. Correction is required. See MPEP § 608.01(b). It is noted that the Applicant replaced and considerably shortened (by deleting seven paragraphs) the "Summary" section of the specification but did not shorten the abstract.

10. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the connection via magnetic material as set forth in claim 43.

11. The disclosure is objected to because of the following informalities: at amended paragraph 84, line 5, it appears that "319" should be --318--. Appropriate correction is required.

### ***Claim Objections***

12. Claims 3, 6-8, 16, 19, 31-38, 47, 49 and 50 are objected to because of the following informalities:

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- a. At claim 3, line 2, it appears that "one or more magnetic field sensors" have already been claimed in claim 1, line 13, as "one or more magnetic sensors".
- b. At claim 6, line 3, it appears that "said magnetic field" should clearly specify which of the two different magnetic fields of claim 1 is referred to.
- c. At claim 7, line 3, it appears that "when" should be deleted.
- d. At claim 16, line 2, it appears that "an present position" should be --a present position--.
- e. At claim 19, line 3, it appears that "sensor" should be --sensors--.
- f. At claim 31, line 3, it appears that "magnet" should be --magnetic-- for consistency.
- g. At claim 32, line 3, it appears that "force" should be --force, --.
- h. Claims 35-37 appear to require further clarification. Some issues are noted below in items i-o.
- i. The recitations of positions and organs should consistently recite either a position of an organ or positions of organs.
- j. At claim 35, line 3, it appears that "comprising orientation of said tool" should clearly recite which element comprises the orientation or should be deleted.
- k. At claim 35, line 3, it appears that "said response" should be --a response--.

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- l. At claim 36, line 4, it appears that data (an abstract element) can not be combined with a set of fiduciary markers (a tangible element) forming stereotactic framing.
- m. At claim 37, line 2, it is stated that x-ray, ultrasound or radar equipment forms said stereotactic frame of reference. However, this relationship is unclear because it appears inconsistent with the recitation that a set of fiduciary markers forms stereotactic framing as set forth in claim 36.
- n. At claim 37, line 3, the relationship between the "frame of reference" and "said stereotactic frame of reference" and "stereotactic framing" is unclear.
- o. At claim 37, lines 4-5, "cardio output, electrocardiogram and pulmonary expansion and contraction" are not organs.
- p. At claim 47, "said temperature sensors" and "said magnetic sensors" lack proper antecedent basis in the claims.
- q. At claim 49, line 2, it appears that "an present position" should be --a present position--.
- r. At claim 50, it appears that "a system controller" has already been recited in claim 39 and should not be claimed as an additional element.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the



art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-20 and 31-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure does not provide support for "wherein at least one pole of each of said first electromagnets is provided to a first common magnetic circuit" and the corresponding limitation for the second common magnetic circuit as set forth in claims 1 and 31. Paragraph 126 discusses closing the magnetic circuit (third magnetic circuit) between the opposing clusters of electromagnets. However, the original disclosure does not provide support for at least one pole of each of said first/second electromagnets being provided to a first/second common magnetic circuit. Therefore, the amended claims 1 and 31 introduce new matter into the application.

15. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure does not support "computed feedback information computed [...] using a previous position input" as set forth in lines 19-20 of claim 1. Paragraphs 90 and 199 discuss feedback information



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using a present position and a desired position, but do not support using a previous position input. Therefore, the computed feedback information computed using a previous position input" as set forth in claim 1 introduces new matter into the application.

16. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure does not support "a position and command input comprising electric current magnitudes and corresponding electric current polarities for said first plurality of electromagnets and said second plurality of electromagnets" as set forth in lines 20-23 of claim 1. Item 12 in paragraph 199 states, "the System Controller SC 302 alters the duty cycle and/or polarity of the modulation inputs to XCA 305, YCA 310, and ZCA 315". However, "a position and command input comprising electric current magnitudes and corresponding electric current polarities for said first plurality of electromagnets and said second plurality of electromagnets" is not supported in the original disclosure. Therefore, this limitation introduces new matter into the application.

17. Claims 4, 40, 41 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

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matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 4, 40 and 41 recite "said distal end comprising one or more ultrasound emitters". However, the original disclosure only supports the distal end comprising "two piezoelectric rings" (see paragraph 140). An ultrasound detector that emits an ultrasonic signal to excite the piezoelectric rings is not located at the distal end. Therefore, claiming "said distal end comprising one or more ultrasound emitters" introduces new matter into the application that is not supported by the original disclosure. In the prior art rejections below, the ultrasound emitters will be interpreted as the piezoelectric rings as was originally disclosed.

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claims 1-20 and 31-50 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20. At claim 1, line 1 and claim 39, line 1, the metes and bounds of the term "catheter-like" can not be determined.

21. At claim 31, line 16, "ultrasonic radiation from said piezoelectric rings" is unclear because the piezoelectric rings do not emit ultrasonic radiation as originally disclosed (see paragraph 17 above).

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22. At claim 39, lines 12-13, the relation of "a previously-computed difference between a previous position of said distal end and said desired position" to the rest of the claim is unclear. For example, it is not clear how the controller can be configured to compute a previously computed difference when the previously computed difference has already been computed.

***Claim Rejections - 35 USC § 102***

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claims 39, 42, 44, 45 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Blume et al. (US 6,014,580). Note that Blume uses the calculations of Werp et al. (US 6,015,414) and incorporates Werp by reference (see Blume, paragraph bridging columns 6 and 7). Blume discloses an apparatus for controlling movement of a tool to be inserted into the body of a patient, comprising: a controllable magnetic field source (12) having a first cluster of electromagnet poles (X+, Y- in figure 4) and a second cluster of electromagnet poles (X-, Y+), said first cluster of poles substantially opposed to said second cluster of poles; a tool (column 5, lines 18-21) having a distal end responsive to said magnetic field; one or more sensors (20) configured to sense a current position of said distal end; and a system controller (112) for controlling said magnetic field source to control a movement of said distal end according to a feedback

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calculation (see formulas in column 6 of Werp) wherein said system controller is configured to compute a difference (error/correction vectors of Werp) between a desired position of said distal end and said current position of said distal end and a previously computed difference between a previous position of said distal end and said desired position. In regards to claims 44 and 50, Blume discloses a Virtual Tip control device (column 8, lines 7-19) to allow user control inputs and that the system controller controls the magnetic field produced by said magnetic field source to cause said distal end to follow movements of the Virtual Tip. In regards to claim 42, the apparatus comprises an operator interface unit (the Virtual Tip). In regards to claim 45, Blume discloses a Virtual Tip and Calibration Fixture Controller (column 8, lines 14-17; "processor" and associated programming).

### ***Claim Rejections - 35 USC § 103***

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

26. Claims 1, 5, 10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580; referred to as "Blume") in view of Blume et al. (US 2001/0021805; referred to as "Blume ('805)") and Haynor et al. (US 6,129,668).

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27. Blume discloses a magnetic field source, a tool, a system controller, an operator interface unit, a Virtual Tip and Calibration Fixture Controller and a Virtual Tip as noted above. The controller of Blume computes feedback information using a present position, a desired position, and a previous position input (Werper, column 6, lines 31-33) to determine a current value (Blume, column 6, lines 55-61). Note that a current value inherently comprises a magnitude and polarity. However, Blume does not expressly disclose a first common magnetic circuit provided to a second common magnetic circuit through a third magnetic circuit.

28. Blume ('805) discloses a first common magnetic circuit (including the circuitry of 14 and the connection between 14 and the unlabelled node below reference 46 in figure 3) provided to a first cluster of magnets (14) and a second common magnetic circuit (including the circuitry of the other element 14 and the connection between 14 and the unlabelled node below reference 46 in figure 3) provided to a second cluster of magnets (14). The two common magnetic circuits are provided to each other by a third magnetic circuit (including circuit of 32 and the connection between 32 and the unlabelled node below reference 46 in figure 3). Note that each element 14 may comprise magnets (paragraph 42, lines 5-7) and therefore can be considered a cluster of magnets. Furthermore, note that the magnets may be electromagnets (paragraph 32, lines 5-7).

29. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used the three magnetic circuits taught by Blume ('805) in the apparatus of Blume in order to provide connections and circuitry for controlling the magnets such that the implanted tool will be moved appropriately.

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30. Furthermore, Blume as modified by Blume ('805) does not expressly disclose one or more magnetic sensors.

31. Haynor teaches one or more magnetic sensors to sense a position of a tool by sensing a magnetic field produced at the tool for the purpose of obviating the need to independently verify positioning with imaging equipment (column 2, lines 42-47).

32. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used one or more magnetic sensors as taught by Haynor in the apparatus of Blume as modified by Blume ('805) in order to determine the position of an indwelling tool without the need for imaging equipment.

33. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Blume et al. (US 2001/0021805) and Haynor et al. (US 6,129,668), as applied to claims 1, 5, 10 and 19 above, and further in view of Nevo (US 6,594,517).

34. Blume as modified by Blume and Haynor discloses PID feedback system (see Werb, column 5, lines 42-47) which equates to a closed-loop feedback system. However, Blume as modified by Blume and Haynor does not expressly disclose a servo.

35. Nevo teaches using a servo with a PID controller (column 8, lines 1-4).

36. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a servo as taught by Nevo to implement the PID feedback system of Blume as modified by Blume and Haynor because servos are well-known implementations of PID controllers.

37. Claims 3, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Blume et al. (US 2001/0021805) and Haynor et al. (US 6,129,668), as applied to claims 1, 5, 10 and 19 above, and further in view of Tanabe et al. (US 5,550,469).

38. Blume as modified by Haynor discloses a calibration fixture (see figures 2 and 3) and a communication controller (54). Note that Haynor discloses that Hall-effect sensors can be used (column 3, line 27). Blume as modified by Blume and Haynor does not expressly disclose one or more temperature sensors.

39. Tanabe teaches a temperature-dependent variable resistor which is considered a temperature sensor for the purpose of compensating the temperature dependence of Hall-effect sensors (abstract). The temperature sensors are paired with the magnetic sensors.

40. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have paired temperature sensors as taught by Tanabe with the Hall-effect sensors of Blume as modified by Blume and Haynor in order to compensate for the temperature dependence of Hall-effect sensors.

41. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Blume et al. (US 2001/0021805) and Haynor et al. (US 6,129,668), as applied to claims 1, 5, 10 and 19 above, and further in view of Solf et al. (US 6,587,709).



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42. Blume as modified Blume and Haynor does not expressly disclose one or more ultrasound emitters which are interpreted as piezoelectric rings (see paragraph 17 above).

43. Solf teaches using piezoelectric rings (10a, 10b, 10c) and an ultrasound emitter (1) for the purpose of automatically tracking a catheter tip without manual displacement of an ultrasound transducer (abstract; column 2, lines 39-46).

44. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used the piezoelectric rings and ultrasound emitter as taught by Solf in the apparatus of Blume as modified by Blume and Haynor in order to automatically and accurately track a catheter tip at all times.

45. Claims 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Blume et al. (US 2001/0021805) and Haynor et al. (US 6,129,668), as applied to claims 1, 5, 10 and 19 above, and further in view of Beyar (US 6,726,675).

46. Blume as modified by Blume and Haynor does not expressly disclose that the Virtual Tip provides tactile feedback.

47. Beyar teaches providing tactile feedback to a control device based on a measured force feedback for the purpose of alerting the physician of an obstruction or obstacle (column 2, lines 38-43). Computed feedback info is based on the measured force feedback.

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48. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have provided tactile feedback as taught by Beyar in the apparatus of Blume as modified by Blume and Haynor in order to alert a physician of an obstruction or obstacle.

49. Claims 11, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Blume et al. (US 2001/0021805) and Haynor et al. (US 6,129,668), as applied to claims 1, 5, 10 and 19 above, and further in view of Hastings et al. (US 2002/0103430).

50. Blume as modified Blume and Haynor does not expressly disclose an X-Axis controller and amplifier, a Y-Axis controller and amplifier, or a Z-Axis controller and amplifier.

51. Hastings teaches an X-Axis controller and amplifier (10), a Y-Axis controller and amplifier (11), and a Z-Axis controller and amplifier (12) for the purpose of independently controlling magnetic coils such that a magnetic dipole can point in any direction in three dimensional space (paragraph 10).

52. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used X-Axis controller and amplifier, a Y-Axis controller and amplifier, and a Z-Axis controller and amplifier as taught by Hastings in the apparatus of Blume as modified by Blume and Haynor in order to independently control magnetic coils such that a magnetic dipole can point in any direction in three dimensional space.

53. Claims 14 and 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Blume et al. (US 2001/0021805), Haynor et al. (US 6,129,668) and Beyar (US 6,726,675), as applied to claims 9 and 20 above, and further in view of Hastings et al. (US 2002/0103430).

54. Blume as modified Blume, Haynor and Beyar does not expressly disclose an X-Axis controller and amplifier, a Y-Axis controller and amplifier, or a Z-Axis controller and amplifier.

55. Hastings teaches an X-Axis controller and amplifier (10), a Y-Axis controller and amplifier (11), and a Z-Axis controller and amplifier (12) for the purpose of independently controlling magnetic coils such that a magnetic dipole can point in any direction in three dimensional space (paragraph 10).

56. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used X-Axis controller and amplifier, a Y-Axis controller and amplifier, and a Z-Axis controller and amplifier as taught by Hastings in the apparatus of Blume as modified by Blume, Haynor and Beyar in order to independently control magnetic coils such that a magnetic dipole can point in any direction in three dimensional space.

57. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Blume et al. (US 2001/0021805), Haynor et al. (US

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6,129,668), Beyar (US 6,726,675) and Hastings et al. (US 2002/0103430), as applied to claims 14 and 15 above, and further in view of Barnes et al. (US 6,038,488).

58. Blume as modified by Haynor, Beyar and Hastings discloses receiving operator switch data (Blume, column 8, lines 12-14) from the Virtual Tip but does not expressly disclose that the Virtual Tip/Calibration Fixture Controller receives encoder position and limit switch data from the Virtual Tip.

59. Barnes teaches receiving encoder position and limit switch data for the purpose of monitoring these signals for tracking the translational and rotational displacement of an object (column 11, lines 27-28).

60. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have received encoder position and limit switch data as taught by Barnes in the apparatus of Blume as modified by Blume, Haynor, Beyar and Hastings in order to monitor these signals for tracking the translational and rotational displacement of an object.

61. Claims 31, 38, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580; referred to as "Blume") in view of Blume et al. (US 2001/0021805; referred to as "Blume ('805)") and Solf et al. (US 6,587,709).

62. Blume discloses an apparatus comprising a magnet source, a tool, a system controller, and a Virtual Tip as noted above. However, Blume does not expressly disclose a first common magnetic circuit provided to a second common magnetic circuit through a third magnetic circuit.

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63. Blume ('805) discloses a first common magnetic circuit (including the circuitry of 14 and the connection between 14 and the unlabelled node below reference 46 in figure 3) provided to a first cluster of magnets (14) and a second common magnetic circuit (including the circuitry of the other element 14 and the connection between 14 and the unlabelled node below reference 46 in figure 3) provided to a second cluster of magnets (14). The two common magnetic circuits are provided to each other by a third magnetic circuit (including circuit of 32 and the connection between 32 and the unlabelled node below reference 46 in figure 3). Note that each element 14 may comprise magnets (paragraph 42, lines 5-7) and therefore can be considered a cluster of magnets.

Furthermore, note that the magnets may be electromagnets (paragraph 32, lines 5-7).

64. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used the three magnetic circuits taught by Blume ('805) in the apparatus of Blume in order to provide the connections and circuitry for controlling the magnets such that the implanted tool will be moved appropriately.

65. Furthermore, Blume as modified by Blume ('805) does not expressly disclose one or more piezoelectric rings or one or more ultrasound emitters which are interpreted as piezoelectric rings (see paragraph 17 above).

66. Self teaches using piezoelectric rings (10a, 10b, 10c) and an ultrasound emitter (1) for the purpose of automatically tracking a catheter tip without manual displacement of an ultrasound transducer (abstract; column 2, lines 39-46).

67. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used the piezoelectric rings and ultrasound emitter as

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taught by Solf in the apparatus of Blume as modified by Blume ('805) in order to automatically and accurately track a catheter tip at all times.

68. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Blume et al. (US 2001/0021805) and Solf et al. (US 6,587,709), as applied to claims 31, 38, 40 and 41 above, and further in view of Nevo (US 6,594,517).

69. Blume as modified by Blume and Solf discloses PID feedback system (see Werp, column 5, lines 42-47) which equates to a closed-loop feedback system. However, Blume as modified by Blume and Solf does not expressly disclose a servo.

70. Nevo teaches using a servo with a PID controller (column 8, lines 1-4).

71. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a servo as taught by Nevo to implement the PID feedback system of Blume as modified by Blume and Solf because servos are well-known implementations of PID controllers.

72. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Blume et al. (US 2001/0021805), Solf et al. (US 6,587,709) and Nevo (US 6,594,517), as applied to claim 32 above, and further in view of Haynor et al. (US 6,129,668) and Tanabe et al. (US 5,550,469).

73. Blume as modified by Blume, Solf and Nevo does not expressly disclose one or more magnetic field sensors.

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74. Haynor teaches one or more Hall-effect magnetic sensors to sense a position of a tool by sensing a magnetic field produced at the tool for the purpose of obviating the need to independently verify positioning with imaging equipment (column 2, lines 42-47).

75. It would have been obvious to one having ordinary skill in the art at the time of invention to have used one or more magnetic sensors as taught by Haynor in the apparatus of Blume as modified by Blume, Solf and Nevo in order to determine the position of an indwelling tool without the need for imaging equipment.

76. Blume as modified by Blume, Solf, Nevo and Haynor does not expressly disclose one or more temperature sensors.

77. Tanabe teaches a temperature-dependent variable resistor which is considered a temperature sensor for the purpose of compensating the temperature dependence of Hall-effect sensors (abstract). The temperature sensor is paired with the magnetic sensors.

78. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have paired temperature sensors as taught by Tanabe with the Hall-effect sensors of Blume as modified by Blume, Solf, Nevo and Haynor in order to compensate for the temperature dependence of Hall-effect sensors.

79. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) in view of Hastings (US 6,148,823).



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80. Blume teaches a communication controller and a calibration fixture as noted above. However, Blume does not expressly disclose that the first cluster of poles is connected to said second cluster of poles by a magnetic material.

81. Hastings teaches that magnetic poles can be connected by magnetic material for the purpose of providing a strong field for a given magnet cost (column 3, lines 39-42).

82. It would have been obvious to one having ordinary skill in the art at the time of invention to have connected the clusters of poles of Blume with magnetic material as taught by Hastings in order to provide a stronger field for a given magnet.

83. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580), and further in view of Haynor et al. (US 6,129,668) and Tanabe et al. (US 5,550,469).

84. Blume does not expressly disclose one or more magnetic field sensors.

85. Haynor teaches one or more Hall-effect magnetic sensors to sense a position of a tool by sensing a magnetic field produced at the tool for the purpose of obviating the need to independently verify positioning with imaging equipment (column 2, lines 42-47).

86. It would have been obvious to one having ordinary skill in the art at the time of invention to have used one or more magnetic sensors as taught by Haynor in the apparatus of Blume in order to determine the position of an indwelling tool without the need for imaging equipment.

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87. Blume as modified by Solf and Haynor does not expressly disclose one or more temperature sensors.

88. Tanabe teaches a temperature-dependent variable resistor which is considered a temperature sensor for the purpose of compensating the temperature dependence of Hall-effect sensors (abstract). The temperature sensor is paired with the magnetic sensors.

89. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have paired temperature sensors as taught by Tanabe with the Hall-effect sensors of Blume as modified by Haynor in order to compensate for the temperature dependence of Hall-effect sensors.

90. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Solf et al. (US 6,587,709), as applied to claims 31, 38, 40 and 41 above, and further in view of Haynor et al. (US 6,129,668) and Tanabe et al. (US 5,550,469).

91. Blume as modified by Solf does not expressly disclose one or more magnetic field sensors.

92. Haynor teaches one or more Hall-effect magnetic sensors to sense a position of a tool by sensing a magnetic field produced at the tool for the purpose of obviating the need to independently verify positioning with imaging equipment (column 2, lines 42-47).

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93. It would have been obvious to one having ordinary skill in the art at the time of invention to have used one or more magnetic sensors as taught by Haynor in the apparatus of Blume as modified by Solf in order to determine the position of an indwelling tool without the need for imaging equipment.

94. Blume as modified by Solf and Haynor does not expressly disclose one or more temperature sensors.

95. Tanabe teaches a temperature-dependent variable resistor which is considered a temperature sensor for the purpose of compensating the temperature dependence of Hall-effect sensors (abstract). The temperature sensor is paired with the magnetic sensors.

96. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have paired temperature sensors as taught by Tanabe with the Hall-effect sensors of Blume as modified by Solf and Haynor in order to compensate for the temperature dependence of Hall-effect sensors.

### ***Response to Arguments***

97. In regards to the drawings being "readable and reproducible for publication purposes", the Examiner respectfully submits that the drawings do not comply with 37 CFR 1.84 (I) as noted above.

98. Applicant argues, on page 43 of the remarks of 7/27/2006, that the metes and bounds of "catheter-like" are readily ascertained from the term itself, the specification, and the nature of the invention. However, the Examiner respectfully submits that the

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term is unclear. For example, it would be unclear if a guide-wire would be considered a "catheter-like tool" because although it has a distal end like a catheter, it may not be hollow like a catheter.

99. Applicant argues that Blume et al. (US 6,014,580) does not teach or suggest a Virtual Tip control device to allow user control inputs or a system controller to control a magnetic field produced by the three-dimensional magnetic field source, to cause the distal end of the tool to follow the movements of a Virtual Tip. Applicant argues that Blume does not teach or suggest a Virtual Tip and Calibration Fixture Controller. Applicant argues that Blume does not teach or suggest a system controller to control a magnetic field produced by the magnetic field source to cause the distal end to follow movements of a Virtual Tip. In response, the Examiner respectfully submits that Blume does teach these elements as noted above in the rejection. In particular, Blume discloses a "virtual catheter" which can be considered a Virtual Tip. Blume states that a processor, which can be considered a "Virtual Tip and Calibration Fixture Controller", converts the bending of the virtual catheter to corresponding magnetic fields to be applied to the distal end that would result in the actual catheter bending in a direction corresponding to that of the virtual catheter (column 8, lines 7-19).

100. Applicant's arguments with respect to the other prior art rejections have been considered but are moot in view of the new ground(s) of rejection.

101. It is noted that the prior art of record does not appear to teach or fairly suggest a correction input such that the distal end moves in substantial unison with a organ as set forth in claims 6 and 35. Wessels et al. (US 6,314,312) teaches guiding a medical

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instrument dependent on movement of an organ but does not teach movement in substantial unison.

102. It is also noted that the prior art of record does not appear to teach or fairly suggest providing tactile feedback according to a position error between a present position of the distal end and a desired position as set forth in claims 16 and 48.

### ***Conclusion***

103. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

104. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

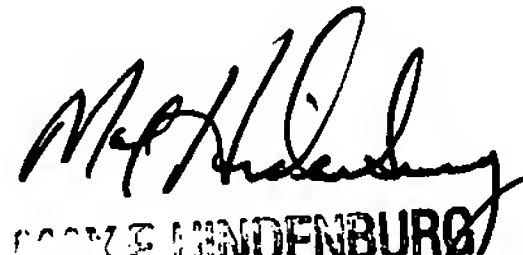
105. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

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106. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

107. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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